

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Naoki Kimura et al.	Art Unit	: 1643
Serial No.	: 10/582,304	Examiner	: Anne Gussow
Filed	: April 20, 2007	Conf. No.	: 4817
Title	: CELL DEATH INDUCING AGENTS		

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

In response to the restriction requirement made in the action mailed November 20, 2008, applicants elect Group I, which encompasses claims 1-7 and 22-28, for examination. Applicants respectfully traverse the restriction requirement with respect to Groups I and II. The Examiner indicated that group II contains claims 8 and 16. Applicants believe the Examiner meant that group II contains claims 8 to 16, as claims 9 to 15 were omitted from the restriction requirement.

The Examiner stated that the “special technical feature recited in claim 1 is an antibody comprising two heavy chain variable regions and two light chain variable regions, wherein the antibody is a single chain polypeptide having a binding activity against HLA.” See, page 2 of the Office Action. The Examiner alleged that this technical feature is not “special” because the Ozaki *et al.* reference (*Blood*, 2003, Vol. 102, No. 11, page 993a) discloses an scfv diabody that binds to HLA.

Applicants respectfully disagree.

Applicants respectfully submit that the claims of Groups I and II comply with the unity of invention requirement as set forth by PCT Rule 13.1. The present specification indicates that an sc(Fv)<sub>2</sub> molecule is a single chain polypeptide antibody that contains two heavy chain variable regions and two light chain variable regions. See, e.g., paragraphs [0064] – [0072]. Accordingly, the claims of Groups I-II are related by the technical features of a) having two heavy chain variable regions and two light chain variable regions and b) being single chain polypeptides. At no point does the Ozaki *et al.* reference disclose a single chain polypeptide that

**CERTIFICATE OF MAILING BY EFS-WEB FILING**

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: December 16, 2008

contains two heavy chain variable regions and two light chain variable regions. Rather, the Ozaki *et al.* reference discloses a single-chain Fv diabody. As indicated in Kortt *et al.*, (*Biomol. Eng.*, 2001, Vol. 18, 95-108; ref. A72 on Form-1449 submitted with the Information Disclosure Statement of May 16, 2007), scFv fragments contain one variable heavy chain (V<sub>H</sub>) domain joined to one variable light chain (V<sub>L</sub>) domain by a linker. When the linker joining the V<sub>H</sub> and V<sub>L</sub> domains is 3 to 10 residues in length, the V<sub>H</sub> and V<sub>L</sub> domains of one scFv associate with those of a second scFv molecule to form a bivalent dimer (i.e., a diabody) made up of two separate polypeptides. See, e.g., page 96 of Kortt *et al.* Thus, the scFv diabody of Ozaki *et al.* does not contain two V<sub>H</sub> and two V<sub>L</sub> regions within a single polypeptide. Applicants respectfully submit that the antibody of the present claims is not anticipated by Ozaki *et al.*, and therefore, constitutes a special technical feature. Thus, Applicants respectfully submit that the claims of Groups I-II meet the requirements for unity of invention, and should be rejoined.

Further, even if the claims of Groups I-II did not meet the requirement for unity of invention according to PCT Rule 13.1, Applicants respectfully submit that searching the claims of Groups I-II as a single group would not impose a serious burden on the Examiner. Under M.P.E.P. § 803, if a search and examination of multiple groups can be made without serious burden, the claims of all those groups are to be examined on the merits. The present claims do not present such a serious burden on the Examiner as to make restriction proper. Groups I-II are drawn to an antibody having two heavy chain variable regions and two light chain variable regions, wherein the antibody is a single chain polypeptide. Similar, if not the same, art classifications would be searched for each Group. Because essentially the same classifications would be searched, there is no undue search burden to the Examiner.

In view of the above, applicants request reconsideration of the restriction requirement and rejoinder of Groups I and II.

Applicant : Naoki Kimura et al.  
Serial No. : 10/582,304  
Filed : April 20, 2007  
Page : 3 of 3

Attorney's Docket No.: 14875-0166US1 / C1-A0323P-US

Apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney  
Docket No.: 14875-0166US1.

Respectfully submitted,

Date: December 16, 2008

/Janis K. Fraser/

Janis K. Fraser, Ph.D., J.D.  
Reg. No. 34,819

Fish & Richardson P.C.  
Customer Number: 26161  
Telephone: (617) 542-5070  
Facsimile: (877) 769-7945

22081616.doc